December 18, 2013

The Honorable Edith Ramirez
Chairwoman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Chairwoman Ramirez:

We, the undersigned consumer, labor and pharmaceutical and biosimilar supply chain industry stakeholders, are writing to express our concern that Risk Evaluation and Mitigation Strategies (REMS) and self-imposed restricted access programs are being used to impede affordable access to generic drugs and biosimilars, thereby denying consumers and federal payors the benefit of robust price competition. We applaud the Federal Trade Commission for its recent initiatives in this area, particularly with respect to the amicus brief filed in the *Actelion* matter, and respectfully urge the FTC to continue its efforts to end this anticompetitive behavior by certain brand pharmaceutical and biotechnology manufacturers, and to restore timely entry of generic drugs and biosimilars to the pharmaceutical marketplace.

In the 112th Congress, Sec. 1131 of S. 3187 (the Food and Drug Administration Safety and Innovation Act, or "FDASIA") sought to address this issue for solely pharmaceutical products under a Food and Drug Administration (FDA) required REMS program. The Congressional Budget Office (CBO) scored the savings to Medicare at $753 million over 10 years. (In fact, we believe the savings will be many multiples of this number.) Although the Senate-passed provision was not ultimately signed into law, it serves as a viable basis for developing a policy that could provide tremendous savings in the SGR package by allowing generic drug manufacturers and biosimilar manufacturers to have access to samples of reference products covered by a REMS program or a self-imposed restricted access program. Due to the failure of this provision to progress in the legislative process, certain pharmaceutical and biopharmaceutical manufacturers claim that Congress does not support closing the REMS loophole, and as a result, access to samples by generic drug and biosimilar manufacturers for testing purposes has been further diminished. Given this turn of events, the FTC's leadership in this area is now more important than ever.

By way of background, the Food and Drug Administration Amendments Act of 2007 (FDAAA) authorized the FDA to implement REMS to ensure that the benefits of a pharmaceutical drug and biologic outweigh its risk by establishing pre-market and post-market safety programs for certain products. REMS programs were initially put in place to control the public distribution of particularly dangerous drugs, attaching extra levels of distribution procedures and warnings for patients receiving the products. Unfortunately, REMS programs are being used to block access to comparator products to halt generic drug and biosimilar product development and are thereby blocking fair and timely generic drug and biosimilar competition.

Generic and biosimilar applicants' access to product samples for testing purposes is critical to ensuring continued access to affordable medicines. However, branded drug and biopharmaceutical companies are increasingly using REMS programs established by the FDA to restrict distribution exclusively to certain entities within the supply chain and to patients,

precluding distribution to generic drug and biosimilar manufacturers. In addition, many companies are using self-imposed restricted access programs, without a formal mandate from FDA, as a tool to restrict distribution, which also results in generic and biosimilar companies' inability to acquire samples for development and testing. Branded companies are also defying instructions from the FDA to collaborate with generic companies in the creation of single shared REMS systems, further obstructing generic entry. Each of these categories of conduct blocks timely competition from generic drugs and biosimilars, and upsets the carefully wrought balance between competition and innovation established in the Hatch Waxman Act and the Biologics Price and Competition Act.

We are deeply appreciative of your Commission's work in this area thus far, and encourage you to continue to help ensure that REMS-related abuses and self-imposed restricted access programs are no longer used to deny affordable generic and biosimilar products to consumers.

At a time of great budgetary challenges for consumers and for the federal government, it is especially important that savings to Medicare and advances in health care delivery ensure that barriers to fair and timely generic drug and biosimilar competition are addressed, and that safe, effective and affordable medicines are made available to consumers.

Thank you for your leadership, and for your consideration of our request.

Sincerely,

Actavis plc
Amneal Pharmaceuticals
Apotex Corp.
BlueCross BlueShield Association
Express Scripts Inc.
Generic Pharmaceutical Association (GPhA)
Hospira, Inc.
Humana
International Union, United Automobile, Aerospace and Agricultural Implement Workers of America (UAW)
Momenta Pharmaceuticals, Inc.
Mylan Inc.
National Association of Chain Drug Stores (NACDS)
National Coalition on Health Care (NCHC)
Pharmaceutical Care Management Association (PCMA)
Portico Benefit Services
Prime Therapeutics
Roxane Laboratories, Inc.
Teva Pharmaceuticals
UAW Retiree Medical Benefits Trust
U.S. Public Interest Research Group (U.S. PIRG)